REMARKS

The Office Action mailed December 13, 2006 has been carefully considered and this paper is responsive thereto. Claims 1-13 and 15-53 are pending in the application.

At page 2 of the Office Action, the Examiner maintained the rejection of claims 1-13, 15-16, 18-19, 21-36, 38-39, 41, 42, 44, 45, 47, 49, 51 and 52 under 35 USC 102(b) as anticipated by Gennadios (U.S Patent 6,214,376).

Applicants again traverse this rejection. Applicants' prior remarks to this rejection filed September 15, 2006 are incorporated herein by reference.

In the remarks in the present Office Action, the Examiner asserts that Gennadios clearly envisages the use of an extruder with a mixer, hence meeting the limitation of step (ii) of claims 1 and 21, feeding the molten composition into at least one of a pump, mixer or devolatilizer. The Examiner stated that support for this view is the disclosure of Gennadios that the composition is transferred to a conventional gelatin encapsulation machine, wherein the films are formed by casting the solution on a cooled rotating drum and the films are fed through a series of rollers to dies which form, cut and fill capsules of various sizes.

A conventional gelatin encapsulation machine is not a mixer, pump or devolatilizer. Gennadios therefore does not disclose step (ii) of claims 1 and 21, feeding the molten composition into at least one of a pump, mixer or devolatilizer, and thus does not anticipate claims 1 and 21 or claims 2-13, 15-20, 41, 42, 44, 45, 51 and 52 which depend directly or indirectly from claim 1, or claims 22-36 29-36, 38 and 39, which depend directly or indirectly from claim 21.

In response to Applicants' arguments that Gennadios does not disclose a highly homogeneous molten composition after heating, the Examiner asserts that the level of heating is not claimed by Applicants, hence application of minor amounts of heat to the viscous mass composition of Gennadios would still result in the formation of a highly viscous composition. The Examiner further attempts to overcome the deficiencies of Gennadios by asserting that the composition claimed by Applicant is identical or similar to that of Gennadios and therefore the properties of the composition of Gennadios are considered to be identical or similar to that claimed by Applicant. These arguments, however, do not cure the deficiencies in the express

teachings of Gennadios. Column 6, lines 1-4 of Gennadios state that when the compositions are prepared at room temperature, they are a very viscous mass (often dough-like), and upon heating, the mass "thins out" and is converted to a clear free-flowing liquid. Gennadios only states that upon heating the mass "thins out" and is converted to a "clear free-flowing liquid." There is nothing in Gennadios that suggests applying a "minor" amount of heat such that the very viscous mass does not thin out, if indeed such a situation would or could occur with the working composition disclosed in Gennadios. In contrast to Gennadios, the homogeneous molten composition formed in the methods of claims 47 and 49 is highly viscous after heating to a temperature at or above the solubilizing temperature of the composition. It is clear that Gennadios does not disclose each and every limitation of claims 47 and 49 and thus does not anticipate these claims.

Withdrawal of this section 102(b) rejection is again respectfully requested.

At page 6 of the Office Action the Examiner maintained the rejection of claims 17 and 37 under 35 USC 103 as being unpatentable over Gennadios (U.S. Patent 6,214,376). In the present Office Action, the Examiner asserts that the amount of pressure applied to the composition is a general condition, and discovering the optimum or workable ranges involves only routine skill in the art.

Applicants again traverse this rejection. Applicants' prior remarks to this rejection filed September 15, 2006 are incorporated herein by reference.

Claims 17 and 37 are directed to the processes of claims 1 and 21, respectively, wherein the solubilizing temperature is greater than the boiling point of the homogeneous molten composition at atmospheric pressure and the heating, hydrating, mixing and solubilizing is conducted above atmospheric pressure.

As Applicants previously argued, there is no disclosure or suggestion in Gennadios of heating the working composition at pressures above atmospheric pressure. Moreover, Gennadios provides no guidance nor identifies a need or reason to vary the pressure at which heating of the working composition is conducted. In the absence of any disclosure, suggestion or motivation, a person skilled in the art would not be led by the teachings of Gennadios to heat the working composition at a pressure greater than atmospheric pressure. Claims 17 and 34 are thus

not obvious in view of Gennadios. Withdrawal of this section 103 rejection is again respectfully requested.

At page 6 of the Office Action, the Examiner maintained the rejection of claims 48 and 50 under 35 USC 103 as being unpatentable over Gennadios (U.S. Patent 6,214,376) as applied to claims 47 and 49, respectively, and further in view of Thanoo (U.S. Patent 5,945,126). In the present Office Action the Examiner alleges that Thanoo provides motivation to combine the references because it discloses the advantages of using a Ross mixture. The Examiner further alleges that Applicants' recognition of another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious.

Applicants again traverse this rejection. Applicants' prior remarks to this rejection filed September 15, 2006 are incorporated herein by reference.

Thanoo is concerned with a process of preparing microspheres wherein small particle sizes can be formed without the problem of foaming. A Ross mixer is disclosed as a useful type of mixer for the process therein because foaming is not a problem when the Ross mixture is used to make the microspheres. Gennadios suggests stirring the working composition, but there is no disclosure or suggestion of using a Ross mixer.

Gennadios and Thanoo are non-analogous art. Although products formed from the processes disclosed in each reference can be used as pharmaceuticals, the types of products formed and the methods used to form the products belong to different arts. It is impermissible to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art. There is no disclosure or suggestion in Thanoo of using the Ross mixer for purposes other than the process of preparing microspheres disclosed therein, much less using a Ross mixer in a process with a film forming composition. The advantage of using a Ross mixer in the process of Thanoo is that foaming is not a problem when preparing microspheres. There is no disclosure or suggestion in Gennadios that foaming is a problem. Persons killed in the art would therefore have no motivation to use a Ross mixer in the method of Gennadios.

Claims 48 and 50 are not obvious over Gennadios in view of Thanoo. There is no teaching, suggestion or motivation in Gennadios or Thanoo, alone or in any combination, to combine the teaching of a Ross mixer in Thanoo with the method of Gennadios. Withdrawal of this section 103 rejection is again respectfully requested.

In view of the above, the present application is believed to be in a condition ready for allowance. Reconsideration of the application is requested and an early Notice of Allowance is earnestly solicited.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 03-2775, under Order No. 10884-00008-US. A duplicate copy of this paper is enclosed.

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Respectfully submitted,

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